PREVU®

NON-INVASIVE SKIN CHOLESTEROL TEST™

PreVu Handheld Spectrophotometer
USER MANUAL

FOR TEST OPERATOR TRAINING AND QUALIFICATION
See Section 7

(English-Canada)

For use with the PreVu® Non-Invasive Skin Cholesterol Point of Care (POC) Test™

This User Manual is strictly intended for use by PreVu Test Operators in Canada

PreVu Customer Service and Support

1-888-928-7205
www.prevu.com

PreVu Handheld Spectrophotometer

(PVU-SPECT-101-UNI)
P101-MA-025-01

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CE

Manufactured by: Miraculins Inc., 6-1250 Waverley Street, Winnipeg, Manitoba, Canada, R3T 6C6

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SECTION 1

Safety, Symbols and Classification

International Compliance

This product complies with the requirements for Electromagnetic Compatibility for Medical Electrical Equipment, IEC 60601-1-2, 2nd Edition, 2001 including Amendment 1/2004.

This product complies with the following electromagnetic emission standards:

- RF Emissions: CISPR 11, Group 1, Class A
- Voltage Fluctuations/Flicker Emissions: Per IEC 61000-3-3

This product complies with the following electromagnetic immunity standards:

- Electrostatic Discharge (ESD), IEC 61000-4-2: Per IEC 60601 Test Level ±6 kV contact, ±8 kV air
- Electrical Fast Transient/Burst, IEC 61000-4-4: Per IEC 60601 Test Level ±2 kV power supply lines, ±1 kV input/output lines
- Surge, IEC 61000-4-5: Per IEC 60601 Test Level ±1 kV differential mode, ±2 kV common mode
- Voltage Dips/Interruptions, IEC 61000-4-11: Per IEC 60601 Test Levels for typical commercial or hospital environment
- Power Frequency Magnetic Field, IEC 61000-4-8: Per IEC Test Level 3 A/m

When connected to a power adapter, the connected equipment must comply with FCC Part 15, subparagraph B, Canadian Standard ICES-003, or international standard IEC 60950 or equivalents.

Symbols and Equipment Classifications

	Manufacturer
	This product has been tested by an authorized testing laboratory, and has been found to meet the applicable standards in Canada and the United States
	This product complies with the essential requirements of the relevant European health, safety and environmental protection directives
	Attention
	Type BF Equipment
	Device and batteries should be disposed of at a proper waste disposal site

Sterilization/Disinfection- Does not apply

Application Safety- Not suitable for use in the presence of flammable anaesthetic

CE Declaration

Manufacturer's Name	Miraculins Inc.
Manufacturer's Address	6-1250 Waverley Street Winnipeg, MB, Canada, R3T 6C6
Model Name	PreVu Handheld Spectrophotometer
Model No.	101
Directive(s) Conformance	IVDD (98/79/EC)
European Authorized Representative	Emergo Europe Molenstraat 15 2513 BH The Hague The Netherlands

- Use Rechargeable Batteries Only (AA NiMH 2300 mAhr minimum). Use of non-rechargeable batteries in this instrument could cause the batteries to overheat and damage the instrument.
- Use UL-listed power adapter to charge the batteries in this instrument (included with instrument).
- Do not use this instrument to measure Skin Cholesterol when connected to the power adapter.
- No user serviceable parts in this product.

NOTE: This Spectrophotometer is intended to be used with the PreVu Non-Invasive Skin Cholesterol Point of Care (POC) Test Reagent Kit only.

SECTION 2

The PreVu Non-Invasive Skin Cholesterol Point of Care (POC) Test

For summary and explanation of the PreVu Non-Invasive Skin Cholesterol Point of Care (POC) Test and principle of procedure, please refer to :

- Section 4 of this User Manual
- The Package Insert included in the PreVu Non-Invasive Skin Cholesterol Point of Care (POC) Test Reagent Kit
- The Training Video CD included with the PreVu Handheld Spectrophotometer
- www.prevu.com

The PreVu® POC Test

SECTION 3

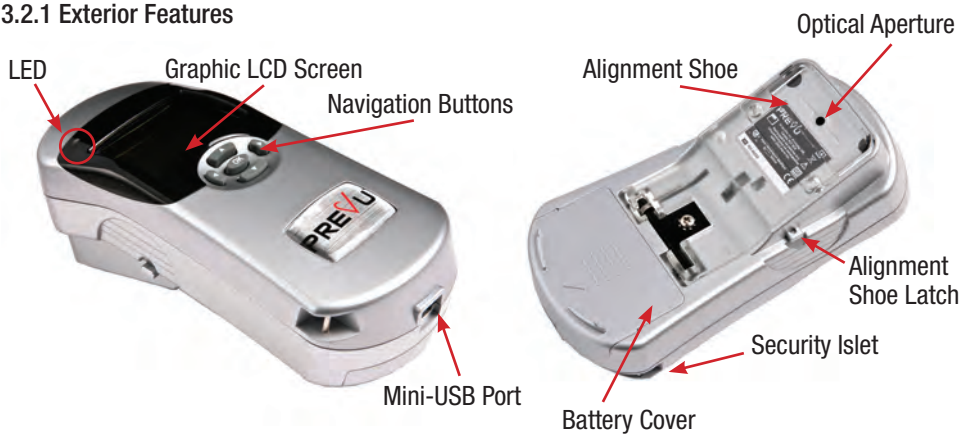
The PreVu Handheld Spectrophotometer

3.1 Spectrophotometer Specifications

Electrical	
Operating voltage (from AC Adapter)	5.0 VDC +/– 0.5 volts, 500 mA
Power Source	2 x AA Rechargeable Batteries (NiMH 2300 mAhr minimum)
AC Power Adapter Accessory	UL-listed AC power adapter, 5 VDC 500 mA
UL Listed and CE-marked Power Adapter Plugs	Phihong Model PSC03R-050 (North American, European and United Kingdom Plugs included)
USB Cable	Mini-B to A-Type USB
Environmental/Misc.	
Operating Temperature	10°C to 40°C (50°F to 104°F)
Operating Relative Humidity	30-70% (non-condensing)
Operating Atmospheric Pressure	700-1060 hPa
Shipping/Storage Temperature	-20°C to 80°C (-4°F to 176°F)
Shipping/Storage Relative Humidity	30-70% (non-condensing)
Shipping/Storage Atmospheric Pressure	500-1060 hPa
Mechanical	
Dimensions	14.8 x 7.2 x 5.0 cm (5.8 x 2.8 x 2.0 in)
Weight	250 grams (0.5 pounds)
Shock and Vibration	Rugged, transportable

3.2 Spectrophotometer Orientation

3.2.1 Exterior Features



3.2.2 The Latch Mechanism

In order to UNLATCH the Alignment Shoe, press the latch mechanism in from the left side of the Spectrophotometer. The alignment shoe will then release. To latch the Alignment Shoe, close the alignment shoe and while holding it in place, push the latch mechanism in from the right side of the Spectrophotometer.

3.3 Preparing the Spectrophotometer

3.3.1 Installing the batteries

Press in and push the battery cover towards the bottom of the Spectrophotometer. Place 2 type AA NiMH rechargeable batteries (2300 mAhr minimum) in the battery compartment. Ensure the batteries are installed as per the polarity indication in the battery compartment. Replace the battery cover.

3.3.2 Charging the batteries

Batteries should be charged using the AC power adapter provided with the Spectrophotometer.

Connect the small (Mini-B) end of the USB Cable into the Mini-USB port on the bottom of the Spectrophotometer. Connect the other end (A-type) to the UL Listed AC power adapter. There are 3 plugs included with the adapter: North American, European and United Kingdom. Select the appropriate plug type and attach it to the adapter. Plug the adapter into the AC wall outlet.

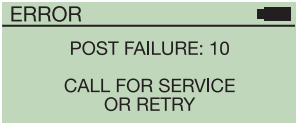
Suitable batteries, UL listed adapter and USB cable are included.

Allow the Spectrophotometer to charge for at least 4 hours when installing new batteries. When the instrument is turned off, and the batteries are charging, the LED will appear red. Please note that the red LED will go out when the unit is turned on after charging is complete. If a low battery warning is displayed on the Spectrophotometer, allow the Spectrophotometer to charge for at least 15 minutes, or replace the batteries with 2 fully charged AA NiMH rechargeable batteries (2300 mAhr minimum). Please refer to **Section 8: Solving Problems: Warnings and Error Messages** for details.

3.4 Turning the Spectrophotometer ON

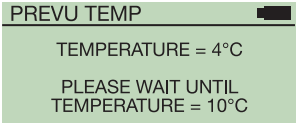
Press and hold OK (centre) button briefly to turn on

3.5 Checking the Spectrophotometer after turning it ON

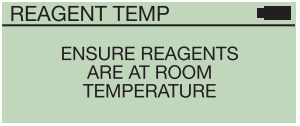


The PreVu Handheld Spectrophotometer performs a Power-On-Self-Test (POST) each time the instrument is turned on. If the POST fails, the unit will display an error message. Please refer to **Section 8: Solving Problems: Warnings and Error Messages** for details.

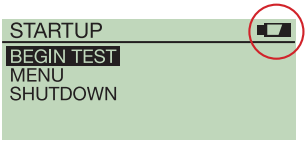
If no errors are detected, the instrument will proceed to the screen showing the PreVu logo.



The operating temperature of the Spectrophotometer must be between 10°C and 40°C (50°F and 104°F). If the temperature of the instrument is not within the specified range, it will display a message indicating the current temperature of the instrument. When the instrument warms or cools to a temperature in the specified range, the startup procedure will automatically proceed.



The Spectrophotometer will display a message reminding the operator that the reagents must be at room temperature. For details please refer to **Section 4.1: Prepare Items Used for the Test.**



The STARTUP Screen will appear.

The battery charge status is shown in the top right corner of the screen. When the battery is charging, the battery charge status symbol will flash.

3.6 Navigation Buttons

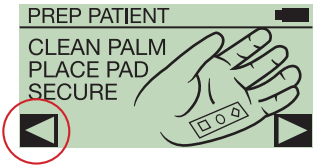
Use the UP & DOWN arrow buttons to scroll through the menu

Press OK (centre) to make selection

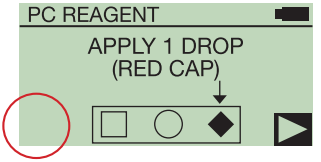
TIP: Holding OK for more than 3 seconds will turn the instrument off at any time.

Use the “NEXT” (RIGHT arrow) button to progress through each step of the PreVu Non-Invasive Skin Cholesterol Point of Care (POC) Test procedure. Upon completion of tasks for the current step, click the RIGHT arrow button to immediately go to the next step.

The “BACK” (LEFT arrow) button allows you to move backward a step.



This is useful if you accidentally selected forward or need to review previous instructions. You should not need to use the back button because the test is designed to run in a forward progression.

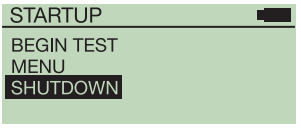


Some screens do not show a “BACK” button and thus you cannot go back to the previous step.

3.7 Turning the Spectrophotometer OFF

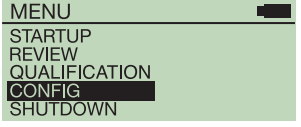
There are 3 options for turning the Spectrophotometer OFF:

1. The Spectrophotometer will automatically shut off after 5 minutes if the Spectrophotometer has not been used.
2. The Spectrophotometer can be manually turned off by pressing and holding the OK button for 3 seconds at anytime.
3. The Spectrophotometer can be turned off by selecting SHUTDOWN on either the STARTUP or MENU screen.



3.8 Setting the Language, Time, Date and LCD Contrast

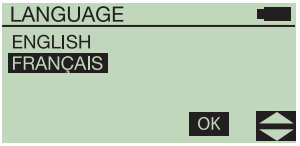
On the STARTUP screen, select MENU



On the MENU screen, select CONFIG (configuration)

3.8.1 Setting the Language

On the CONFIG screen, select LANGUAGE

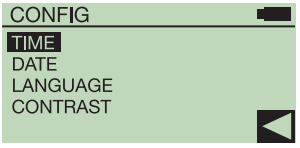


Use the UP and DOWN arrows to highlight the appropriate language. Press OK button to select the language.

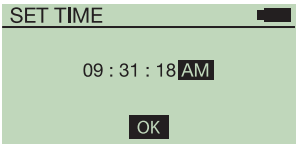
3.8.2 Setting the Time and Date

NOTE: The Time and Date must be set each time the batteries are removed or replaced.

Setting the time

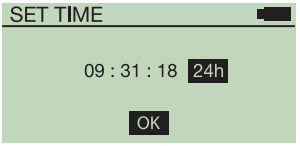


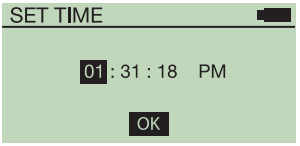
On the CONFIG screen, select TIME.



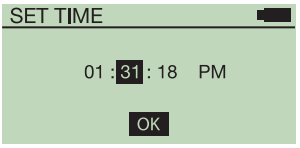
There are two clock settings: AM/PM and 24 hr

Use the RIGHT arrow button to highlight AM and then use the UP and DOWN arrow buttons to select either AM (AM/PM) or 24 hr. For the AM/PM clock, PM times can be selected by increasing the hour past 12-noon.

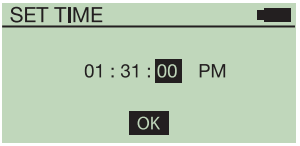




Use the RIGHT or LEFT arrow button to select the hour. Use the UP and DOWN arrow buttons to set the hour.



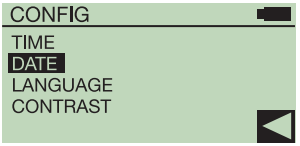
After setting the hour, press the RIGHT arrow button and use the UP and DOWN arrow buttons to set the minute.



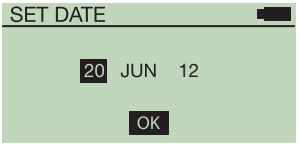
Follow the same procedure to set the second.

When the correct time is set, press the OK button to save the changes.

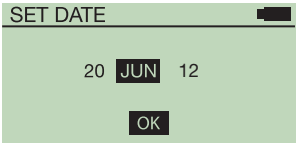
Setting the Date



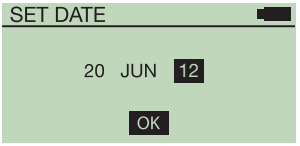
On the CONFIG screen, select DATE.



Use the UP and DOWN arrow buttons to select the day.

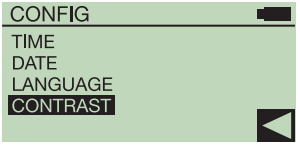


After setting the day, press the RIGHT arrow button and use the UP and DOWN arrow buttons to select the month.



After setting the month, press the RIGHT arrow button and use the UP and DOWN arrow buttons to select the year. When the correct date is set, press OK button to save the changes.

3.8.3 Setting the LCD Contrast



On the CONFIG screen, select CONTRAST.

Use the UP and DOWN arrow buttons to darken and lighten the contrast. When a desired contrast is achieved, press OK button to save the setting.

3.8.4 Turning on the Qualification Mode

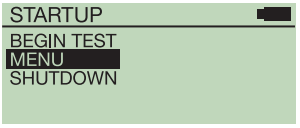
Turning on the Qualification Mode enables the PreVu Handheld Spectrophotometer to display patient test scores on its screen as numerical values, to assist PreVu Test Operators during the training and qualification stage. Please refer to **Section 7: PreVu Test Operator Training and Qualification** for a full description of the training and qualification procedure.

Under Normal Operating (default) Mode settings, the PreVu Handheld Spectrophotometer displays patient test results by category, relaying a **Normal, Elevated** or **Borderline** Skin Cholesterol level. This is based upon a patient's test score falling within a defined numerical range, which is measured and recorded by the instrument and then translated into a category description for the screen display. Patients are then accordingly advised what category they are in and the results are interpreted by the PreVu Test Operator (see **Section 5.2: Interpretation of Test Results**). Patients are not provided with their individual numerical test scores as a matter of course – only the range they have tested within - as it is the category placement overall that determines potential next-steps on a clinical level.

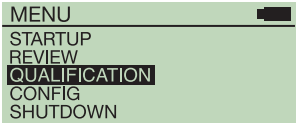
However, during the training and qualification stage, PreVu Test Operators do require access to a patient's individual numerical test score in order to enter this data at www.prevu.com to demonstrate that they are able to obtain correct Skin Cholesterol results, as determined by comparison to established references values. The series of numerical test scores entered online by the PreVu Test Operator are then automatically calculated to determine PreVu Test Operator proficiency and their qualification to begin testing actual patients.

The steps below outline the procedure for temporarily turning on the Qualification Mode of the PreVu Handheld Spectrophotometer so that individual, numerical test scores (i.e. 95, 82, 115) display on the Spectrophotometer screen in place of the category test results (Normal, Elevated, Borderline). PreVu Test Operators can then enter this data at www.prevu.com under the PreVu test Operator Training and Qualification section of the web site, when doing qualification testing on their final three test volunteers.

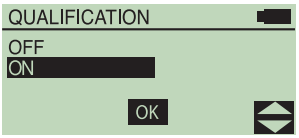
When the PreVu Handheld Spectrophotometer is turned off or shuts down on its own, it defaults back to Normal Operating Mode displaying the category test results.



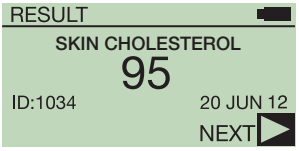
On the STARTUP screen, select MENU



On the MENU screen, select Qualification



On the QUALIFICATION screen use the Up or Down arrow button to highlight the Qualification Mode setting as being ON or OFF. Press OK button to save the setting.



In Qualification Mode, the RESULT screen will display the patient's individual, numerical test score.

3.9 Spectrophotometer Intended Use Environments and Users

The PreVu Handheld Spectrophotometer is intended for use with the PreVu Non-Invasive Skin Cholesterol Point of Care (POC) Test in environments usually including, but not limited to doctors' offices, nursing stations, pharmacies, health and fitness clubs, employee and corporate health assessment centres, mobile health assessment units, community health fairs and other permanent and temporary clinical service settings accessible by the general public.

The PreVu Handheld Spectrophotometer is intended to be used by any individual who has been trained and qualified in its proper operation for use with the PreVu Non-Invasive Skin Cholesterol Point of Care (POC) Test (see **Section 7: PreVu Test Operator Training and Qualification**), for testing in environments as referred to above. Such individuals would usually include, but not be limited to doctors, nurses, doctors' assistants, lab technicians, pharmacists, pharmacist technicians, dieticians, general staff and other individuals both with and without formal medical training.

SECTION 4

Performing the PreVu Non-Invasive Skin Cholesterol Point of Care (POC) Test Using the PreVu Handheld Spectrophotometer

NOTE: Read this section and the PreVu Non-Invasive Skin Cholesterol Point of Care (POC) Test Reagent Kit Package Insert carefully before testing. Also view the Training Video CD or the Training Video presentations at www.prevu.com.

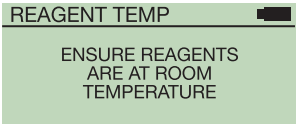
4.1 Prepare Items Used for the Test

The following items should be readily available:

- At least 1 absorbent tissue will be needed for each test (not supplied in Reagent Kit). Ensure that they are non-lotion, lint-free tissues.
- Wet-Nap® moist towelette
- Alcohol swab
- Foam test pad
- Reagents
- Blotting stick

Bring the reagent bottles to room temperature (approximately 18 to 25°Celsius or 64 to 77°Fahrenheit)

Remove reagents from kit and bring to room temperature at least 30 minutes prior to testing patient. Once the testing day is completed the reagents need to be returned to the refrigerator for overnight storage.

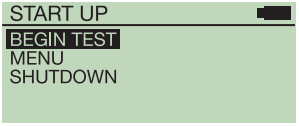


When the PreVu Handheld Spectrophotometer is turned ON, a reminder screen will appear for 5 seconds.

Set up for test as follows:

1. Remove caps on all bottles and line the bottles up in the following order: Detector, PC (Positive Control) and Indicator... or Green, Red and Blue by bottle cap and label colours shown. This is the order they will be used in the test.
2. Place one absorbent tissue in front of the patient.
3. Have available a Wet-Nap® moist towelette, alcohol swab, foam pad and blotting stick.

4.2 Proceeding with the Test

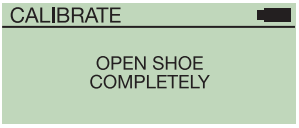


When the STARTUP screen appears, select BEGIN TEST.

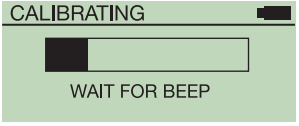
NOTE: Also review **Section 6: Guidelines for Optimum Test Performance** in addition to the steps that follow below.

Step 1: CALIBRATION

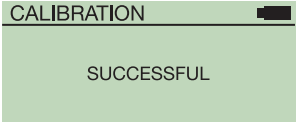
Prior to each test, the instrument must be calibrated.



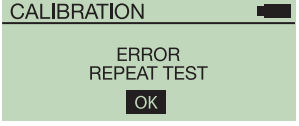
CALIBRATE: If the shoe is locked shut, unlatch the shoe, and then open the shoe completely.



When the shoe is fully open, the CALIBRATING screen will appear. It is important that the shoe remains fully open until the calibration is complete.



When calibration is complete, you will hear a short beep, and if calibration was successful, the screen will show SUCCESSFUL.



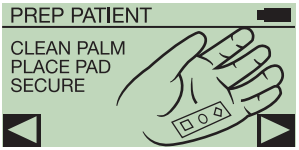
If calibration was not successful , the instrument will indicate to repeat the procedure.

Please refer to **Section 8: Solving Problems: Warnings and Error Messages** if the calibration error persists.

TIP: Place Spectrophotometer back on table *after* calibration.

Step 2: PREPARE PATIENT

Perform the following steps to properly clean the patient's hand and apply the foam pad.



CLEAN PALM

- Make sure that the patient washes their hands vigorously with soap and water OR vigorously clean the outside portion of palm of one hand with the Wet-Nap® moist towelette that is provided. NOTE: Do not use other brands of moist towelette to clean palm.
- Dry the palm using a clean paper towel or other absorbent, lint-free tissue.
- Wipe the outside portion of the palm of the hand vigorously with an alcohol swab and wait about 30 seconds for the cleaned area to air dry. Keep the alcohol swab for use after the test.

NOTE: Palm must be completely dry before proceeding with the next step.

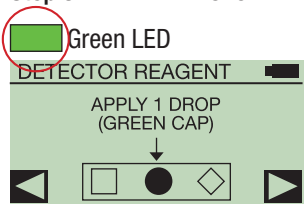
PLACE FOAM PAD & SECURE

- Remove protective liner from the foam pad and firmly place the pad on the hypothenar eminence where the palm was cleaned with the alcohol swab (see diagram above).
- You will note the foam pad contains three different shaped wells: square, round, and diamond.
- Place the diamond well toward the fingers as shown in the screen image above.
- Avoid placing the foam pad on prominent creases of the palm. Ask patient to invert palm on absorbent tissue and firmly press down to secure pad. Ensure the foam pad is firmly stuck to the palm by checking the edges of the foam pad.
- Press RIGHT arrow button to proceed to next screen.

TIP: Use the palm of the hand of the patient that is the same as your dominant hand for ease in performing the test (i.e. use the patient's right hand if you are right handed).

NOTE: Full test procedure can be viewed on the Training Video CD and at www.prevu.com. The PreVu POC Test Reagent Kit contains enough reagent for 40 tests, plus some additional reagent for unintentional wastage. Keeping count of the number of tests performed will help PreVu Test Operators know when they are coming to the end of their reagent supply.

Step 3: APPLY DETECTOR REAGENT



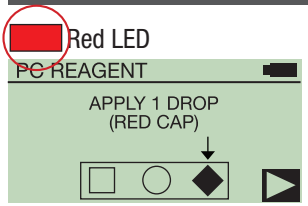
One drop of the Detector (green cap) must be applied to the round test well (centre well). The LED to the top left of the screen will appear green (corresponding to the green cap of the Detector).

It is important that only one drop be added to the proper well. Apply the Detector by hovering the tip of the dropper bottle over the well without touching it and then dispensing one drop cleanly into the well.

NOTE: Press RIGHT arrow button IMMEDIATELY after addition of Detector to proceed to next screen. It is important that the Detector has exactly one minute to react before it is removed.

TIP:

- Angle reagent bottle at 45°.
- Do not touch the skin with bottle tip.
- If any liquid ends up on the foam pad, dry it off gently with a clean absorbent tissue.
- Check to confirm there has been no reagent leakage around the base of the foam pad where it meets the skin. If there is leakage at any point during the test, discontinue the test immediately.
- Do not test the same hand again for a 24-hour period. You must use the patient's opposite hand for the second test within 24 hours

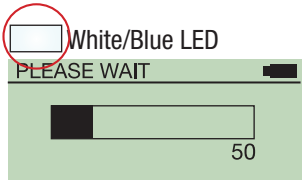


Step 4: APPLY PC REAGENT

Immediately after screen appears add one drop of Positive Control (PC) (red cap) to the diamond shaped well. The LED to the top left of the screen will appear red (corresponding to the red cap of the PC Reagent).

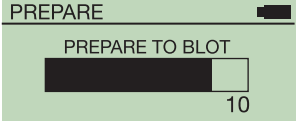
NOTE: It is important that NO liquid should be added to the square well at this time.

The hand should be held still for the ensuing one minute incubation period. The PC Reagent screen will appear for a maximum of 10 seconds. If you have completed the PC step earlier than the 10 seconds, the screen can be advanced by pressing the RIGHT arrow button.



The LED light on the top left of the screen will flash white/blue during the wait time.

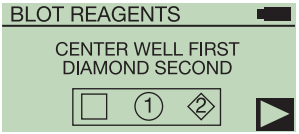
After 10 seconds, or if the screen is advanced manually, the timing bar will display on the screen. The number to the bottom right of the bar indicates the number of seconds remaining. The LED will flash white/blue until the reaction time has expired.



"PREPARE"
When the Detector has been incubating for 50 seconds (10 seconds remaining), you will hear a short beep, and you will be prompted to PREPARE TO BLOT.

CRITICAL STEP

Step 5: BLOT REAGENTS



After the one minute timer expires, you will hear a long beep. You will be prompted to "BLOT REAGENTS".

Firmly blot the liquid from the Detector (round) and PC (diamond) wells of the foam pad.

Slowly insert one end of the double-ended blotting stick into the round centre well of the foam pad to absorb the Detector Reagent.

After insertion press firmly and hold for 3 seconds to ensure all excess Detector Reagent has been absorbed then invert blotting stick and insert second (clean and unused) end into the same round well (centre well) of the Foam Pad.

Press to make firm contact and gently twist the blotting stick approximately one quarter of a turn forward and then back while still making contact with the palm. Once the round centre well has been blotted dry, remove the blotting stick and slowly insert the second end into the diamond-shaped well to absorb the excess PC Reagent. Discard the blotting stick.

Press RIGHT arrow button to proceed to next screen.

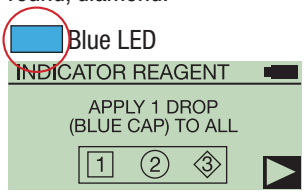
CAUTION: Blot round (centre) well first, blot diamond well second.

Visually inspect wells to ensure all liquid has been removed. It is important to remove ALL liquid from BOTH the centre (round) and diamond wells.

NOTE: Blotting directions also presented on the Training Video CD and at www.prevu.com and in Section 6: Guidelines for Optimum Test Performance.

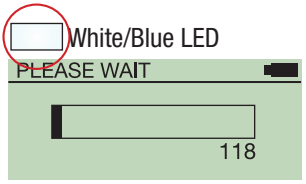
Step 6: APPLY INDICATOR REAGENT

Apply one drop of Indicator (blue cap) to ALL three wells in the following order: square, round, diamond.



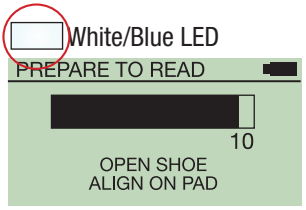
The LED to the top left of the screen will appear blue (corresponding to the blue cap of the Indicator Reagent).

NOTE: After applying the Indicator to all wells, you must IMMEDIATELY proceed to the next step by pressing the RIGHT arrow button.

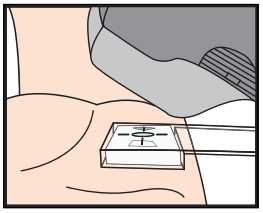


"PLEASE WAIT"
After the Indicator has been applied to all three wells, the patient must hold their hand steady and level for 2 minutes (120 seconds). The timing bar, and the number of seconds remaining will appear on the screen.

The LED to the top left of the screen will flash white/blue during this time. It is important that the solutions incubate for exactly two minutes before the measurement is taken.

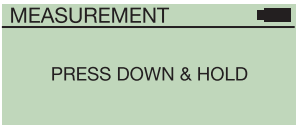


"PREPARE TO READ"
When 10 seconds remain, you will hear a short beep, and the screen will ask you to OPEN SHOE & ALIGN ON PAD.

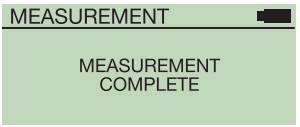


"ALIGN ON PAD"
Hold the shoe of the Spectrophotometer perpendicular to the foam pad. Position the Spectrophotometer such that the rectangular inset on the Spectrophotometer shoe fits securely around the foam pad with the target window on the plastic shoe directly over the round well in the centre of the foam pad.

Step 7: MEASUREMENT

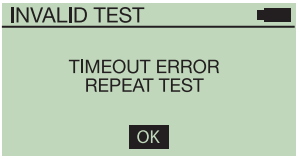


Just prior to the end of 2 minutes, you will hear two short and one long beep, and the screen will show PRESS DOWN & HOLD.



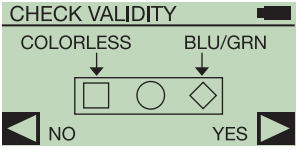
Depress and hold the instrument over the centre well until the instrument shows MEASUREMENT COMPLETE.

TIP: Do not lift the device off the palm until the screen changes to "MEASUREMENT COMPLETE".

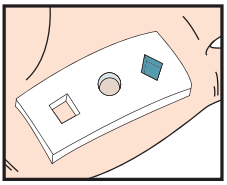


It is IMPORTANT that the measurement is taken IMMEDIATELY after the 2 minute timer expires. If the measurement is not taken until 2 minutes and 10 seconds (the very outside incubation range), the screen will show INVALID TEST and it will ask you to REPEAT the TEST, which then must be done on the patient's other palm if conducted within a 24-hour period.

Step 8: CHECK VALIDITY



You must visually confirm if the test is valid or not by looking at the outer control wells (square and diamond).

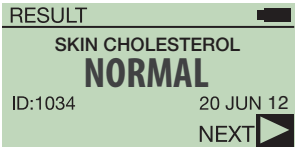


The test is considered VALID when it meets the following criteria:

1. The liquid in the square well is colorless
2. The liquid in the diamond well is blue/green

VALID TEST RESULT

If the test does meet the two criteria defined above, press the (YES) RIGHT arrow button to indicate that the test is VALID.



Upon completion of a valid test, the Skin Cholesterol Level will appear on the RESULT screen.

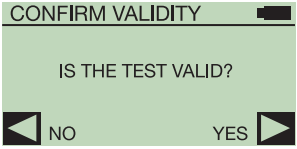
On the RESULT screen, you will see:

- Skin Cholesterol Level
- Unique 4 digit ID
- Date the test was performed

When you are finished with the current test result, and have recorded down the data showing on the screen, press the (NEXT) RIGHT arrow button to continue.

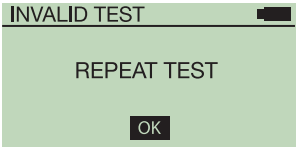
INVALID TEST RESULT

If the test is NOT VALID according to the criteria defined above, press the (NO) LEFT arrow button.



To be completely sure, the screen will prompt you to CONFIRM VALIDITY; IS THE TEST VALID? Reinspect the wells of the foam pad and answer the question on the screen. If the test does not meet the 2 criteria defined above, press the (NO) LEFT arrow button to confirm that the test is NOT VALID.

(Note: If the test is VALID, please press the (YES) RIGHT arrow button to proceed to VALID TEST RESULT Section above.)



The INVALID TEST screen will appear, asking you to REPEAT TEST. When OK is pressed, the screen will prompt you to CALIBRATE the instrument and then prepare the patient for the next test.

Step 9: CLEAN PALM & DEVICE

You MUST clean the patient's hand and the instrument (Alignment Shoe) whenever you complete a valid test or abort a test after reagents have been applied to the patient. Use the alcohol swab you saved at the beginning of the test and an absorbent tissue to clean and dry the palm, and an absorbent tissue to dry the Alignment Shoe.

NOTE: If you will be immediately performing another test on the same patient, you must use their other hand OR wait 24 hrs before performing another test on the same hand.

Cleaning up the Patient

To ensure the patient is properly cleaned after a test is completed (or aborted), perform the following steps:

- Invert palm on absorbent tissue to remove liquid from wells.
- Peel off pad.
- Clean palm with alcohol swab saved from the beginning of the test.
- Dry with absorbent tissue.

Cleaning up the Spectrophotometer

To avoid contaminating future tests, it is important that you properly clean your instrument after a test is completed (or aborted). To remove any chemical residue from the previous test, simply clean your instrument (Alignment Shoe) with a dry absorbent tissue.

Please refer to **Section 9: Spectrophotometer Support and Care**.

WARNING: DO NOT allow any liquid into the Spectrophotometer during cleanup, especially the Optical Aperture (see page 10).

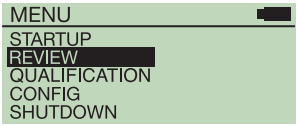
The screen will remain on the instrument for 5 seconds, or alternatively, it can be advanced by pressing the (NEXT) RIGHT arrow button.

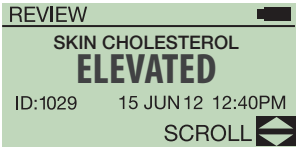
You are now ready to perform the next PreVu Non-Invasive Skin Cholesterol Point of Care (POC) Test.

SECTION 5

Reviewing Test Results

5.1 Accessing Stored Results





It is possible to recall the 10 most recent test results. To view the results, select REVIEW from the MENU screen.

The screen will show the result of the most recent test performed. The screen will display the unique 4-digit ID #, the date and time the test was performed, and the Skin Cholesterol Level.

The previous test results (category format only: **Normal**, **Elevated** and **Borderline**), can be reviewed by pressing the UP arrow button.

To return to the MENU screen, press the OK button.

In Qualification Mode, while numerical test scores are displayed on screen during the test for the benefit of PreVu Test Operators in training, numerical test scores cannot be accessed afterwards under REVIEW. PreVu Test Operators are advised to record numerical test scores at the time of the test to enter them online for qualification at www.prevu.com, please refer to **Section 7: PreVu Test Operator Training and Qualification.**

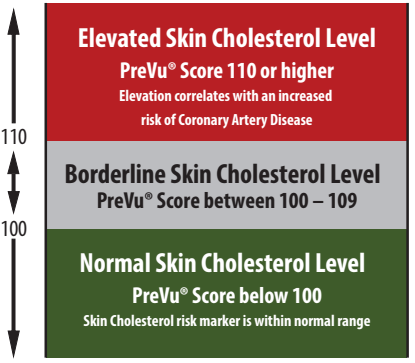
5.2 Interpretation of PreVu Test Results

The degree of colour hue measured during the PreVu POC Test is proportional to the amount of bound Skin Cholesterol on the surface of the skin, and places the patient on a scale showing their risk of coronary artery disease based on the clinical data for the biomarker.

A Skin Cholesterol value of 110 is chosen (based on clinical studies) as the value at which patients begin to acquire an increased burden of risk of coronary artery disease.

The PreVu Handheld Spectrophotometer displays patient test results as being either **Normal**, **Elevated** or **Borderline** based upon a patient's reading falling within a defined numerical range, which the instrument measures and records internally.

The adjacent table presents an outline of the three categories of PreVu Test results.


110
100
Elevated Skin Cholesterol Level
PreVu® Score 110 or higher
Elevation correlates with an increased risk of Coronary Artery Disease
Borderline Skin Cholesterol Level
PreVu® Score between 100 – 109
Normal Skin Cholesterol Level
PreVu® Score below 100
Skin Cholesterol risk marker is within normal range

For more information on how these categories are to be interpreted for patients, please visit **www.prevu.com**.

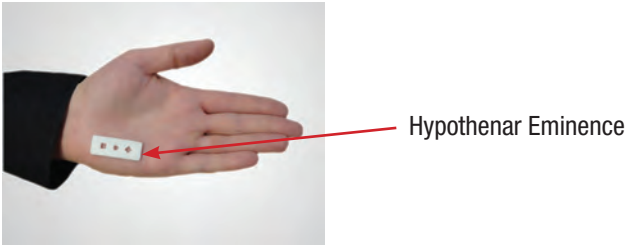
SECTION 6

Guidelines for Optimum Test Performance

This section presents a series of guidelines for best test performance, which will be of assistance in helping a PreVu Test Operator become more comfortable with conducting the PreVu Non-Invasive Skin Cholesterol Point of Care (POC) Test. It will also assist in helping you complete the training and obtain qualification (see **Section 7: PreVu Test Operator Training and Qualification**), which is required prior to being able to test an actual patient.

6.1 Foam Pad Handling and Placement

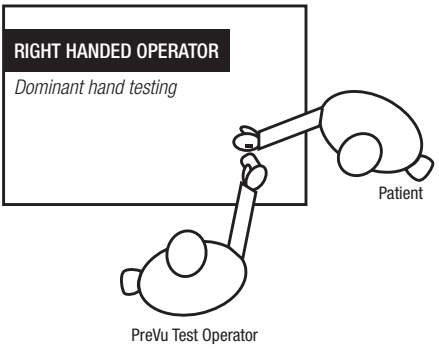
- When peeling the protective backing off the foam pad and placing the pad onto the patient's hand, the PreVu Test Operator must take care not to come into contact with the adhesive backing.
- Peel back a portion of the foam pad, positioning the square well towards the patient, and place this portion on the patient's hand first, removing the balance of the protective backing while at the same time laying down the remainder of the foam pad.
- Ensure the foam pad is laid down on the palm without being stretched or pulled from end to end.
- Do not place the wells of the foam pad over creases on the palm of the hand. Creases on the palm of the hand increase the chance of reagent leakage along the edges of the pad which will result in an Invalid Test result.
- Place the foam pad on the hypothenar eminence of the palm as indicated in the below diagram, with the diamond well towards the fingers as shown in the image below.

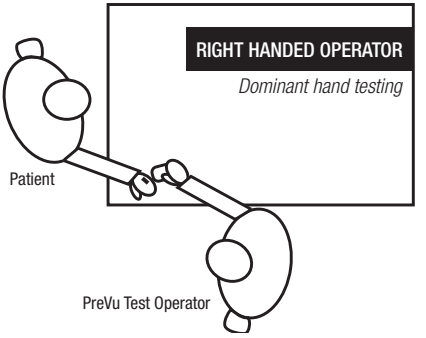


- The test should be performed with appropriate overhead lighting to ensure that the visual reading of the negative (square) and positive control (diamond) wells of the foam pad is carried out accurately.

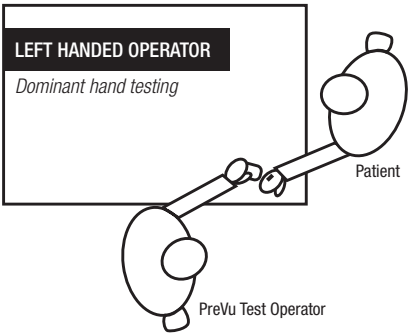
6.2 Test Operator and Patient Seating Positions – Dominant Hand Testing

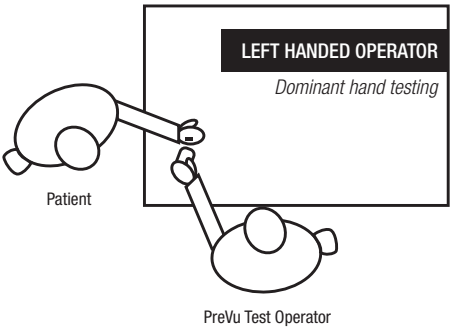
- The test should be performed seated at a table and the PreVu Test Operator should be positioned at the right or left corner of the table with the subject seated on the adjacent side.
- The PreVu Test Operator should hold the PreVu Handheld Spectrophotometer in his/her dominant hand and test the same hand on the patient. In this manner, if you are right handed you should hold the Spectrophotometer in your right hand and test the patient's right hand. If the left hand is your dominant hand, you should hold the Spectrophotometer in your left hand and test the patient's left hand. This is to ensure the best positioning of the Spectrophotometer possible to take the skin cholesterol reading, and a steady hand to achieve a stable and level fit of the Alignment Shoe over top of the foam pad.
- The below diagrams show the optimum PreVu Test Operator and patient seating positions for a right-handed operator (dominant hand), seated at both a right corner table and left corner table configuration and testing the patient's right hand. In all diagrams, please note the location of the foam pad on the patient's hypothenar eminence (represented by the black strip), and the Spectrophotometer held in the PreVu Test Operator's dominant hand.



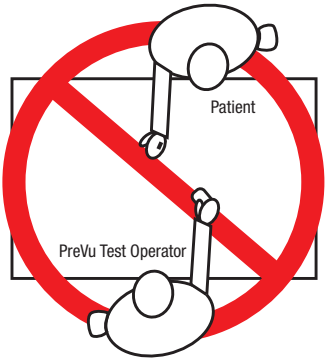


- The below diagrams show the optimum PreVu Test Operator and patient seating positions for a left-handed operator (dominant hand), seated at both a right corner table and left corner table configuration and testing the patient's left hand.



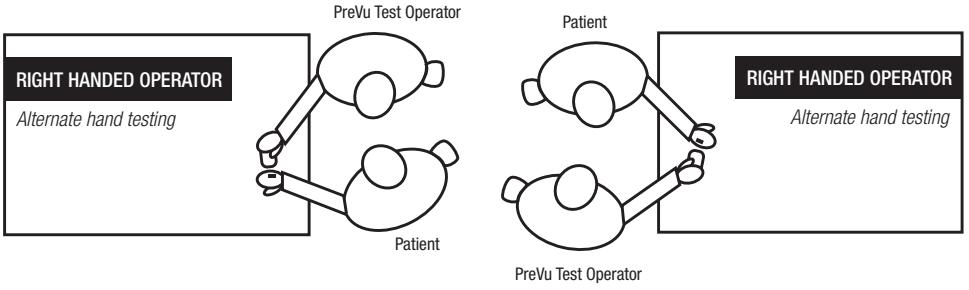


- Avoid seating the patient across the table as demonstrated in the diagram below. This could necessitate stretching and limit dexterity and balance during the blotting and reading portions of the test and result in an Invalid Test result.

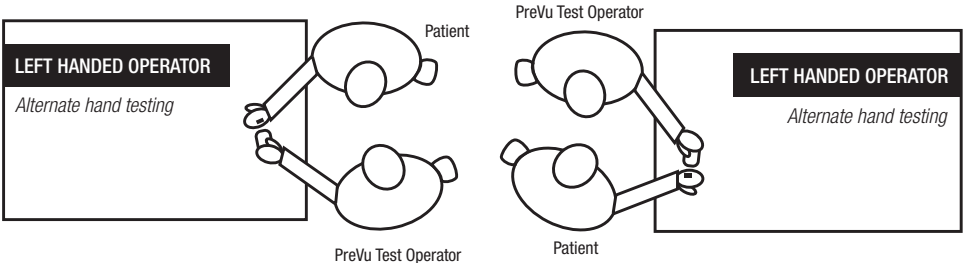


6.3 Test Operator and Patient Seating Positions – Alternate Hand Testing

- If the first test conducted is determined to be an Invalid Test result and you wish to run a second test immediately, you must conduct that second test on the patient's opposite hand. The same hand may not be tested again for a 24 hour period due to the risk of reagent residue on the palm from the first test interfering with the second test reading.
- To ensure that the correct test procedure continues to be followed (the PreVu Test Operator continuing to use his/her dominant hand in holding the PreVu Handheld Spectrophotometer and the skin cholesterol reading not being taken across the palm from the thumb side, (see **Section 6.6 Reading the Skin Cholesterol Level**)) the PreVu Test Operator and the patient must change positions.
- The diagram below shows the best repositioning for a right-handed PreVu Test Operator and patient, seated at both a right corner table and left corner table configuration, to conduct an alternate hand test (testing the patient's left hand). This position is not as natural as the position for a dominant hand test, but it will still allow for the correct procedure to be followed.



- The diagram below shows the best repositioning for a left-handed PreVu Test Operator and patient, seated at both a right corner table and left corner table configuration, to conduct an alternate hand test (testing the patient's right hand). This position is not as natural as the position for a dominant hand test, but it will still allow for the correct procedure to be followed.



6.4 Reagent Dropper Bottles

- The reagents are provided in dropper bottles with a special tip to control the flow of reagent to the precise amount needed for the test, which is achieved by firmly yet slowly squeezing the bottle between the thumb and index finger until the drop builds and cleanly detaches from the dropper bottle tip.
- The PreVu Test Operator should practice squeezing out several drops of reagent onto a paper towel to get a feel for the squeezing pressure required to generate full, clean drops.
- If the dropper bottle tip appears wet or has a small droplet at the tip prior to the test, dry the tip with an absorbent, lint-free tissue. If the other dropper bottles are also wet or have droplets on their tips, these should be dried as well with great care taken not to cross-contaminate the tips by wiping them with the same section of tissue that has already been used to wipe another dropper bottle tip. Dropper bottle tips can become wet if the bottles are stored on their sides or turned upside down. Ideal storage is vertical configuration of all dropper bottles.
- Suspend the dropper bottle at a 45° angle so that the tip is just above the centre of the foam pad wells, without touching the foam pad itself. The drop should be targeted to free-fall into the centre of the well. Do not rest the dropper bottle on the side of the foam pad well when dispensing the drops as this can lead to the drops being drawn back onto the foam pad instead of into the well.
- At no time should any of the bottle dropper tips come into contact with the skin at the base of the foam pad wells or anywhere on the palm.
- If any liquid ends up on the foam pad, dry it off gently with a clean absorbent tissue.
- Visually confirm throughout all stages of the test that no reagent leakage has occurred around the base of the foam pad where it meets the skin. If reagent leakage occurs discontinue the test immediately and repeat it on the alternate palm, or wait 24 hours and test the same palm once again.

- Reagent leakage seldom occurs and can be the result of a patient's excess perspiration, the insufficient washing of the palm prior to testing, or the application of the foam pad to a palm that was not yet completely dry from the use of the alcohol swab. If reagent leakage persists on the patient's alternate palm, a correct reading may not be possible.
- It is important for the consistency of test results that full drops of reagent be cleanly deposited into the foam pad test wells and that the presence of any air bubbles in the centre well is minimized. Any air bubbles will need to be dissipated.
- If you see bubbles present on top or at the bottom of the liquid in the centre well, you can try gently tapping the side of the foam pad with your finger to dissipate the bubbles. There must be no air bubbles to interfere with the binding of the Detector or the skin cholesterol reading, which is taken by the Spectrophotometer when a beam of light shines straight down out of the Optical Aperture and into the centre well and through the reagent fluid.
- Bubbles appearing in any of the wells except the centre well, are inconsequential and should not be of any concern.
- If while squeezing out the drops, the dropper bottle tip appears bubbly or foamy, this may mean you have reached the end of the dropper bottle contents and may not be able to deploy sufficient reagent to conduct the test, or to continue it.
- If this occurs prior to the reagent being dropped and no reagent has come into contact with the patient's hand, source a new bottle (at room temperature) to conduct the test. If the same situation occurs and reagent has already partially come into contact with the palm, and a replacement bottle is not immediately available at room temperature, the test must be aborted as the extended incubation period due to delays will result in an INVALID TEST result.

6.5 Blotting

- The PreVu Test Operator must employ a consistent blotting technique as demonstrated in the Training Video CD and the Training Video presentations at www.prevu.com. A deviation in blotting technique from the prescribed norm can result in inaccurate skin cholesterol readings being taken and an incorrect result.
- The downward pressure of the blotting stick when first inserted into the centre foam pad well for three seconds, should be firm enough to visually depress the skin to ensure all the unbound reagent is removed, but not so hard as to cause the foam pad to detach from the palm at the base of the foam well. This will cause liquid to become trapped underneath the foam pad leading to an incorrect result.
- When reversing the blotting stick and placing the other end into the centre well once again, ensure that when twisting the blotting stick a quarter turn clockwise and then counter-clockwise back, that care is taken not to exceed twisting the blotting stick any further than the quarter turn prescribed.
- Given the diameter of the blotting stick, a quarter turn is a very small twist and you should take care in focusing your attention on the top of the blotting stick to try and best approximate the quarter turn by visually tracking the rotation forward and backward. Again, the twisting is intended to further assist the blotting stick's built-in fluid draw capability and must not be overdone, nor the blotting stick depressed too firmly while twisting, as this too can result in removing Detector that has already bound to the skin.

- When blotting the diamond shaped well, move the blotting stick from corner to corner inside the well while maintaining contact with the skin to ensure all the excess Positive Control Reagent is removed. The square shaped well which is the Negative Control, is never dried by the blotting stick.
- Practice blotting on your own hand to get the feel for firm, but not undue pressure. Again, the goal is to dry up any excess fluid in the well and the blotting sticks have been designed to instantly draw up the fluid. The depression and twisting of the blotting stick therefore is intended to *assist* with the fluid drawing action, but must not result in removing reagent that has already bound to the skin surface by being too firmly depressed. This can lead to inaccurate test results being taken and an incorrect result.

6.6 Reading the Skin Cholesterol Level

- Prior to reading the skin cholesterol level, visually confirm that no reagent leakage has occurred around the base of the foam pad where it meets the skin. If reagent leakage occurs discontinue the test immediately and repeat it on the alternate palm, or wait 24 hours and test the same palm once again.
- The skin cholesterol reading must be taken with the PreVu Handheld Spectrophotometer approaching the hypothenar eminence where the foam pad sits, from off of the edge of the bottom of the palm. The reading must never be taken with the Spectrophotometer crossing over the full palm of the hand from the thumb side down as this will result in a poor fit of the Alignment Shoe along with an inability to hold the Spectrophotometer level, resulting in an Invalid Test result. The images below demonstrate both the correct and incorrect way to position the Spectrophotometer while taking the skin cholesterol measurement.

Correct Reading

Incorrect Reading

- When preparing for and taking the reading, you should place your non-dominant hand beneath the patient's hand for support, and maintain the palm as straight out and level as possible as the reader is depressed, or alternatively, ensure the palm is properly balanced resting directly on the table.
- You should be ready to position the Spectrophotometer over the palm prior to the reading taking place (you will have ten seconds to do this after the beep prompts you), taking care to fit the Alignment Shoe precisely over top of and down onto the foam pad, without causing the Alignment Shoe to close and without disturbing the fluid in the foam pad wells.

- You will notice that the Alignment Shoe features an inset space at its leading, clear plastic edge designed to receive the foam pad, and that it is the same size and depth of the foam pad with a hole to be targeted directly over the centre well. This recess is where the foam pad retreats into when the Alignment Shoe is placed snugly over top of it and where it remains during the skin cholesterol reading.
- When it is time to take the reading, and with the Alignment Shoe retaining its precise fit over the foam pad, you will gently press the Spectrophotometer down towards the palm closing the shoe in the process. This needs to be done while ensuring that the Alignment Shoe remains as perfectly level as possible to the palm and the foam pad throughout, and with the palm remaining level as well.
- You will notice that the Spectrophotometer is ergonomically designed with a slight bend at the section where the Alignment Shoe is attached. This allows the hand to more comfortably hold the device. When the Alignment Shoe is fitted to the foam pad and the skin cholesterol reading is in process, it is this top portion of the Spectrophotometer that must remain level with the foam pad and the palm – the bottom portion of the device will naturally be pointed downward slightly and off the palm as a result.
- You must take care not to press the Spectrophotometer down too hard onto the palm while the skin cholesterol reading is taking place. While some slight compression of the foam pad may occur, care should be taken not to compress the foam pad such that fluid could escape the wells and contaminate the reading. A gentle pressing down of the Spectrophotometer so that the Alignment Shoe closes completely onto the palm of the patient's hand during the skin cholesterol reading is all that is required.
- Some wetness of the Alignment Shoe and of the top of the foam pad around the wells post-reading is not abnormal and will occasionally occur.
- Sometimes while cleaning a patient's hand or the Alignment Shoe post-test, your hands may come into contact with reagent from the just conducted test. If this occurs, you should wash your hands thoroughly or wipe them with a Wet Nap® moist towelette to avoid contaminating the next test when handling the new patient's palm, or the foam pad and blotting stick.

SECTION 7

PreVu Test Operator Training And Qualification

Before testing actual patients, it is the responsibility of all persons conducting the PreVu Non-Invasive Skin Cholesterol Point of Care (POC) Test to ensure they have successfully completed the prescribed training and are qualified to test. Miraculins Inc. has established a protocol to formally train PreVu Test Operators and to address qualification through www.prevu.com.

PreVu Test Operators must demonstrate that they are able to obtain correct Skin Cholesterol results, as determined by comparison to established reference values.

7.1 Training and Qualification Procedure

7.1.1 Training Review

Read and ensure that you understand all sections of this PreVu Handheld Spectrophotometer User Manual and view the Training Video CD included with the PreVu Handheld Spectrophotometer or the Training Video presentation at www.prevu.com under the PreVu Test Operator Training and Qualification section.

7.1.2 Practicing the Test

Practice conducting the test on a sufficient number of volunteers utilizing the reagents and test materials provided in the PreVu Test Operator Training Kit, until you are comfortable with the testing technique. Test volunteers must be advised that the skin cholesterol readings generated are strictly for demonstration and practice purposes only and may not represent accurate results.

7.1.3 Qualification Testing

For final qualification, place Spectrophotometer into Qualification Mode to access numerical patient test scores (see **Section 3.8.4: Turning on the Qualification Mode**), test three final volunteers (not actual patients) on both palms, and record the numerical results (for convenience) on the Test Sheet that can be printed out at www.prevu.com. Test volunteers must be advised that the skin cholesterol readings generated are strictly for demonstration and practice purposes only and may not represent accurate results.

Please note that numerical test scores cannot be accessed afterwards under REVIEW, so PreVu Test Operators are advised to record test volunteer scores on the Test Sheet provided at the time of testing for each of the three final test volunteers. In REVIEW test results are only available in category format: **Normal**, **Elevated** or **Borderline**.

See **Section 5.1: Accessing Stored Results** for further information.

7.1.4 Login

Obtain a login name and password at www.prevu.com under the PreVu Test Operator Training and Qualification section.

7.1.5 Submit Results

Submit the numerical results from the three qualification test subjects in the fields provided.

7.1.6 Qualification Criteria

Once the results are submitted at www.prevu.com, the PreVu Test Operator will be considered to have successfully completed training, provided the following criteria has been met and the PreVu Test Operator has received confirmation of same by email:

a. The coefficient of variation (CV) between the tests conducted on two palms is less than 20%.

b. The mean skin cholesterol value for all three volunteers (six results) is less than 120.

NOTE: If the CV is greater than 20% or the mean skin cholesterol value for all three volunteers is greater than 120, the PreVu Test Operator will be asked to review the Training Video CD or the Training Video presentation at www.prevu.com. The PreVu Test Operator will also be asked to go back and review the PreVu Handheld Spectrophotometer User Manual, and practice on additional volunteers before repeating qualification testing on three final test volunteers and submitting the data results once again.

7.1.7 Qualification Confirmation

When results satisfy the criteria outlined above, an email will be sent to the PreVu Test Operator confirming that he/she has successfully completed training and is now qualified as being ready to conduct the PreVu Non-Invasive Skin Cholesterol Test Point of Care (POC) Test on patients.

7.1.8 PreVu Test Operator Training and Qualification Summary

The PreVu Test Operator should confirm that he/she:

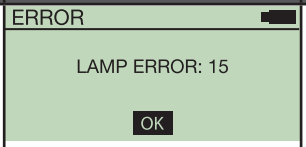
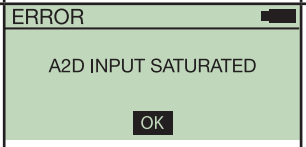
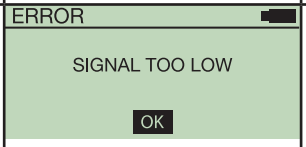
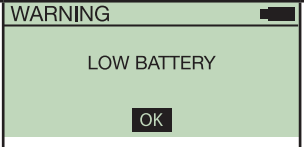
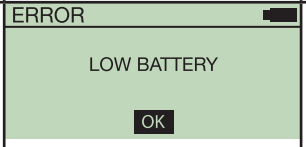
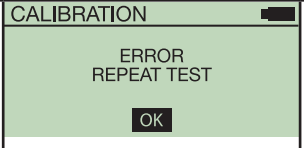
- has thoroughly reviewed and understands the training materials for the PreVu Non-Invasive Skin Cholesterol Point of Care (POC) Test;
- has tested a sufficient number of volunteers to acquire familiarity of the testing process and to perfect the testing technique;
- has tested and recorded three final volunteers for qualification and submitted their results to www.prevu.com; and
- WILL NOT start testing actual patients until they receive email confirmation from www.prevu.com that they have successfully completed training and have been qualified to conduct the PreVu Non-Invasive Skin Cholesterol Test Point of Care (POC) Test on patients.

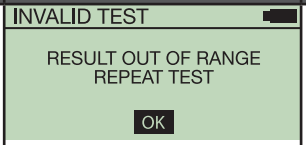
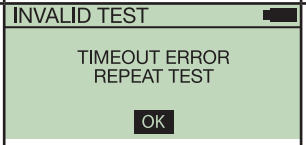
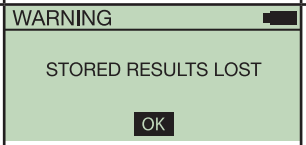
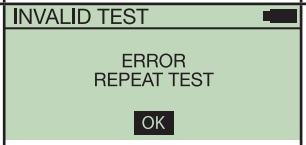
SECTION 8

Solving Problems: Warnings and Error Messages

The following is a summary of Warnings and Error Messages that may be displayed on the PreVu Handheld Spectrophotometer screen. In the event of a problem, please refer to the information under the Message, What it Means, and User Action columns. If further assistance is required, please contact PreVu Customer Service & Support at 1-888-928-7205 (Canada) or visit www.prevu.com.

No.	Message	What it Means	User Action
1	PREVU TEMP TEMPERATURE = 8°C PLEASE WAIT UNTIL TEMPERATURE = 10°C	The Spectrophotometer temperature is less than 10ºC (50ºF). Wait until the device reaches a temperature within the operating range of 10ºC to 40ºC (50ºF to 104ºF).	Wait until the Spectrophotometer warms up. The Reagent Temp screen will appear once the operating temperature is reached.
2	Flash ERROR TEMPERATURE = 70°C OVER TEMPERATURE CALL FOR SERVICE OR RETRY	The Spectrophotometer has detected that the temperature is out of operating range of 10ºC to 40ºC (50ºF to 104ºF) during the startup test or during operation.	Turn Spectrophotometer off and check the room temperature. Turn the unit back on after it has adjusted within the operating range. If the error message appears again, contact PreVu Customer Service & Support. If it is over 30ºC (86ºF) and the batteries must be charged, then charge with the instrument turned off.
3	Flash ERROR POST FAILURE: 03 CALL FOR SERVICE OR RETRY	Hardware Error	Turn Spectrophotometer off and then back on. If error message appears again, contact PreVu Customer Service & Support.
4	ERROR LAMP FAILURE: 12 OK	Hardware Error	Turn Spectrophotometer off and then back on. If error message appears again, contact PreVu Customer Service & Support.

No.	Message	What it Means	User Action
5		Hardware Error	Turn Spectrophotometer off and then back on. If error message appears again, contact PreVu Customer Service & Support.
6		Hardware Error	Turn Spectrophotometer off and then back on. If error message appears again, contact PreVu Customer Service & Support.
7		Hardware Error	Turn Spectrophotometer off and then back on. If error message appears again, contact PreVu Customer Service & Support.
8		Battery is too low.	Plug in the Spectrophotometer for at least 15 minutes or replace the batteries with 2 fully charged AA rechargeable batteries (refer to section 3.3.1 and 3.3.2 of this manual for further instruction)
9		The battery level is too low to perform a test.	Plug in the Spectrophotometer for at least 15 minutes or replace the batteries with 2 fully charged AA rechargeable batteries (refer to section 3.3.1 and 3.3.2 of this manual for further instruction)
10		Calibration error during the start of the new test.	Press the OK button to return to the CALIBRATION screen. Repeat Calibration procedure. If the Calibration Error message appears again, contact PreVu Customer Service and Support.

No.	Message	What it Means	User Action
11		Skin Cholesterol value out of the preset Skin Cholesterol range.	Refer to the Package Insert of the PreVu Non-Invasive Skin Cholesterol Point of Care (POC) Test Reagent Kit, to ensure the test is performed properly, and then repeat test.
12		Timeout (late) during the measurement.	Repeat the test (if conducted within 24 hours test must be done on patient's other palm), ensuring that the measurement is taken within 10 seconds of when the 2 minute (Indicator) timer expires.
13		Hardware error.	Turn Spectrophotometer off and then back on. Use the MENU>REVIEW to see results. If error message appears again, contact PreVu Customer Service and Support.
14		Shoe opened during measurement.	Repeat the test. Use care to keep the shoe closed during the measurement.

SECTION 9

Spectrophotometer Support and Care

9.1 Warranty and Repair Information

For information about Instrument Warranty and Repair, please contact PreVu Customer Service and Support at 1-888-928-7205 (Canada) or visit www.prevu.com.

9.2 Spectrophotometer Care

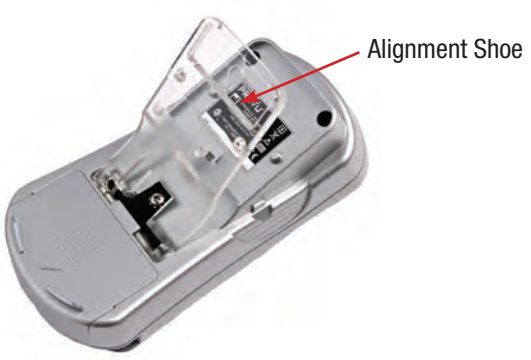
- Keep the instrument clean
- Do not immerse in water or other liquid
- Do not put any liquid into the Optical Aperture on the bottom of the instrument

9.3 Cleaning Instructions

- Use a cloth lightly dampened with water and mild detergent to wipe down the outside of the instrument
- Remove all liquid from the alignment shoe after each test

9.4 Alignment Shoe Replacement

The Alignment Shoe may be subject to wear from regular movement. If necessary, to inquire about replacing your Alignment Shoe, please contact PreVu Customer Service and Support.



PreVu Customer Service and Support

1-888-928-7205
www.prevu.com

PreVu Handheld Spectrophotometer

(PVU-SPECT-101-UNI)
P101-MA-025-01

This User Manual is strictly intended for use by PreVu Test Operators in Canada.

CE

Manufactured by: Miraculins Inc., 6-1250 Waverley Street, Winnipeg, Manitoba, Canada, R3T 6C6

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